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10/728,267	12/04/2003	William M. Appling	P-37/500622.20040	7104

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REED SMITH, LLP
ATTN: PATENT RECORDS DEPARTMENT
599 LEXINGTON AVENUE, 29TH FLOOR
NEW YORK, NY 10022-7650

EXAMINER

KOHARSKI, CHRISTOPHER

ART UNIT	PAPER NUMBER
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3763

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/728,267	Applicant(s) APPLING, WILLIAM M.	
	Examiner CHRISTOPHER D. KOHARSKI	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 December 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6-9, 23 and 26-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6-9, 23 and 26-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

Examiner acknowledges the reply filed 12/03/2007 in which claims 6-9 and 23 were amended and new claims 26-36 were added. Examiner additionally acknowledges the amended specification [0037] that was filed. Currently claims 6-9, 23 and 26-36 are pending for examination in this application.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, *the transition section of shorter or longer length relative the distal and proximal segments* must be shown or the feature(s) canceled from the claim(s) (claims 35-36). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New

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Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 32 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant's specification states background information that CT injections through PICC lines may be as high as 300 psi and have warnings that advise against conditions over 100psi [00034], whereas Applicant's inventive section states a range of "up to 300 psi" [00036], *thus the range of 100-300 psi burst strength is an unsupported range and is considered new matter.*

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 6, 9, 26-29, 31, 33 and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Chee et al. (USPN5,542,937). Chee et al. discloses a multilumen extruded catheter.

Regarding claims 6, 9, 26-29, 31, 33 and 36, Chee et al. discloses a catheter capable of central venous insertion and higher pressures comprising: a proximal tube segment (118, 134) containing a first polymer material of a first durometer (HDPE); a distal tube segment (116, 130) containing a second polymer material of a second durometer (LDPE) (col 4, ln 45-55), the proximal tube segment being stiffer than the distal tube segment; and a relatively short (relative to the proximal and distal) transition tube segment (112, 132) interposed between the proximal tube segment and the distal tube segment; and wherein the transition tube segment is composed of both the first polymer material and the second polymer material (col 4, ln 35-45); and wherein the amount of second polymer material of the transition tube segment continuously decreases from the distal tube segment to the proximal tube segment and the amount of the first polymer material continuously increases from the distal tube segment to the proximal tube segment and the durometer of the polymer material contained in the transition tube segment continuously decreases from the proximal end of the transition tube segment to the distal end of the transition tube segment; and wherein said catheter shaft is of non-reinforced single layer unitary construction (Figures 1-2, col 4, ln 50-60), the proximal, distal and transition tube segments together defining a single integrally formed tube with one or more lumens (102, 103, 110, 108) that can be either neat or filled (Figures 1-12).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

or

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 6, 9, 26-29, 31, 33 and 36 are rejected under 35 U.S.C. 102(e) as being anticipated by Wang (USPN6,648,024). Wang discloses a co-extruded tubular product.

Regarding claims 6, 9, 26-29, 31, 33 and 36, Wang discloses a catheter capable of central venous insertion and higher pressures comprising: a proximal tube segment (113) containing a first polymer material of a first durometer; a distal tube segment (115) containing a second polymer material of a second durometer the proximal tube segment

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being stiffer than the distal tube segment; and a relatively short (relative to the proximal and distal) transition tube segment (114) interposed between the proximal tube segment and the distal tube segment; and wherein the transition tube segment is composed of both the first polymer material and the second polymer material (col 8); and wherein the amount of second polymer material of the transition tube segment continuously decreases from the distal tube segment to the proximal tube segment and the amount of the first polymer material continuously increases from the distal tube segment to the proximal tube segment and the durometer of the polymer material contained in the transition tube segment continuously decreases from the proximal end of the transition tube segment to the distal end of the transition tube segment; and wherein said catheter shaft is of non-reinforced single layer unitary construction (Figures 14-15, col 8), the proximal, distal and transition tube segments together defining a single integrally formed tube with one or more lumens (Figures 1-18.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

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2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 7-8, 23, 30, and 34 are rejected under 35 U.S.C 103(a) as being unpatentable over Chee et al. (or Wang) in view of Parker (USPN5,769,830). Chee et al. (or Wang) meets the claim limitations as described above except for the variable transition segment containing radiopaque filler and a hub component.

However, Parker teaches a soft tip guiding catheter.

Regarding claims 7-8, 23, 30, and 34, Parker teaches a catheter (10) for insertion into the body comprising a multi-segment zone with a proximal end comprising (27) 10-30% weight percent of radiopaque marker and a distal end (32) with a 35-60% weight percent of radiopaque marker and a transition zone (near 15) in which the radiopaque filler varies during the transition of the two materials that make up each end with an attached hub component (30) (Figures 1-4).

At the time of the invention, it would have been obvious to add the catheter hub and radiopaque filler of Parker et al. to the system of Chee et al. (or Wang) in order to allow for optimal catheter tracking and visualization of the tip and body with a hub for infusion fluids. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Parker et al. (cols 1-2).

Claim Rejections - 35 USC § 103

Claims 32 and 35 are rejected under 35 U.S.C 103(a) as being unpatentable over Chee et al. (or Wang).

Regarding claims 32 and 35, Chee et al. (or Wang) discloses the claimed invention except for the catheter burst pressure and the transition segment length. It would have been obvious to one having ordinary skill in the art at the time the invention was made to optimize the catheter wall thickness to have a burst pressure resistance of 100-300 psi and transition long zone length to withstand the pressures during which the procedure that catheter is used creates, and since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960). Additionally, it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Response to Arguments

Applicant's arguments with respect to claims 6-9, 23 and 26-36 have been considered but are moot in view of the new ground(s) of rejection necessitated by Applicant's amendment.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Koharski whose telephone number is 571-272-7230. The examiner can normally be reached on 5:30am to 2:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Date: 2/18/2008

/Christopher D Koharski/
Examiner, Art Unit 3763

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763